

Remarks

Claims 1-18 were previously pending in the subject application. By this Amendment, claims 1 and 13 have been amended and claims 4, 7-12 and 14-18 have been cancelled. Accordingly, claims 1-3, 5, 6 and 13 are now before the Examiner for consideration. In view of the remarks and amendment set forth herein, favorable consideration of the claims now presented is earnestly solicited.

As an initial matter, the applicant acknowledges that the subject matter of previous claims 7-12 is withdrawn as being directed to a non-elected invention. By this Amendment, the non-elected subject matter has been canceled without prejudice.

In order to expedite prosecution, the claims have now been amended to lend greater specificity and clarity to the claimed subject matter. These amendments are made solely for the purpose of expediting prosecution and should not be taken to indicate the applicant's agreement with, or acquiescence in, the rejections of record.

Claim 4 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. By this amendment, claim 4 has been cancelled and claim 1 amended to address the issue raised by the Examiner. Accordingly, the applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §112 in view of the applicant's cancellation of claim 4 and amendment to claim 1.

Claims 13-18 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claim 13 has been amended to delete the term "in need of such treatment." Accordingly, the applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §112 in view of the applicant's amendment to claim 13.

Claims 1-6 and 13-18 have been rejected under 35 U.S.C. §112, first paragraph. The applicant respectfully traverses this grounds for rejection because the subject application provides ample guidance for a person skilled in the art to make and use the subject invention as claimed.

Initially, the applicant respectfully submits that the claims now presented are quite narrowly tailored. The claims recite one very specific dipeptide for use in a very simple method to enhance a

specific type of immunity. Please note that, in order to add even greater clarity to the claimed invention, the claims have been amended herein to specify that the enhanced immunity is achieved by increasing mucosal IgA immunity.

Thus, the invention involves a simple composition that is easily formulated and administered. The applicant respectfully submits that, the fact that the prior art did not suggest this invention (as noted at pages 8-10 of the Office Action) does not make the art, as a whole, unpredictable. In any event, in view of the applicant's clarification that the enhanced immunity is specifically achieved through an increase in IgA mucosal immunity, the applicant believes that any issues of enablement have been addressed. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection set forth under 35 U.S.C. §112, first paragraph.

Claims 1-3 have been rejected under 35 U.S.C. 102(b) as being anticipated by Miyazawa *et al.*, 1976 (Journal of the Faculty of Fisheries and Animal Husbandry Hiroshima, Vol. 15(2):161-169). The applicant respectfully traverses this grounds for rejection because Miyazawa *et al.* do not disclose or suggest the current invention. Please note that the limitation of previous claim 4 (not included in this rejection) have been added to claim 1.

It is a basic premise of the Patent Law that, to anticipate, a single reference must, within its four corners, disclose all of the limitations of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra; Kalman /v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

In *Dewey & Almy Chem. Co. v. Mimex Co.*, Judge Learned Hand wrote:

No doctrine of the patent law is better established than that a prior patent . . . to be an anticipation must bear within its four corners adequate directions for the practice [of the subsequent invention] . . . if the earlier disclosure offers no more than a starting point . . . if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. 124 F.2d 986, 990; 52 USPQ 138 (2nd Cir. 1942).

The Miyazawa *et al.* reference does not disclose or suggest the composition as currently claimed. Therefore, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on the Miyazawa *et al.* reference.

Claims 1-6 have been rejected under 35 U.S.C. §102(b) as being anticipated by JP-2119762 patent. As noted above, for a rejection to be proper under 35 U.S.C. §102, a single prior art reference must disclose, within its four corners, all of the elements of the claimed invention. The JP-2119762 patent does not disclose the applicant's particular advantageous composition that consists essentially of a specific advantageous dipeptide present at a specified concentration.

The applicant respectfully points out that for a claim to be anticipated under the principles of inherency, the subject of a single prior art reference must necessarily function in accordance with the limitations of the claim. *In re King*, 801 F2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Further,

the doctrine of inherency is available only when the prior inherent event can be established as a certainty. That an event may result from a given set of circumstances is not sufficient to establish anticipation. . . . A prior inherent event cannot be established based on speculation, or where a doubt exists (emphasis added). *Ethyl Molded Product Co. v. Betts Package Inc.*, 9 USPQ 2d 1001, 1032-33 (E.D. KY 1988).

The cited reference does not, either explicitly or inherently, disclose a composition that consists essentially of the arginyl-glutamine dipeptide at the claimed concentration.

Therefore, the applicant respectfully requests reconsideration and withdrawal of the rejection set forth under 35 U.S.C. §102 based on the JP-2119762 reference.

Claims 1-6 and 13-18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over JP-2119762 taken with WO 98/09985 and Neu *et al.* (The *FASEB Journal* 10:829-837, June 1966). The applicant respectfully traverses this grounds for rejection because the cited references do not disclose or suggest the claimed invention. Nor is there any motivation in the cited art to modify the teachings found in these references to arrive at the current invention.

A finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. Here, the cited references do not contain a suggestion of the current invention. It is only the applicant's disclosure that provides such a teaching, and the applicant's disclosure cannot be used to reconstruct the prior art for a rejection under §103. This was specifically recognized by the CCPA in *In re Sponnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Srock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

The JP '762 document contains, at pages 5-6, the following disclosure:

... the present invention is concerned with a nutrient composition formulated with an essential amino acid, a non-essential amino acid and at least one oligopeptide elected from the group consisting of a dipeptide and a tripeptide containing L-glutamine residue, which at least contains, when said oligopeptide is converted into amino acids, the following amino acids in the following compositional range:

<u>Amino Acid</u>	<u>Compositional Range (g/100 g of total amino acids)</u>
L-isoleucine	4.0 - 13.0
L-leucine	10.0 - 20.0
L-lysine	3.5 - 13.0
L-methionine	1.5 - 10.0
L-phenylalanine	3.0 - 10.0
L-threonine	3.0 - 11.0

<u>Amino Acid</u>	Compositional Range (g/100 g of total amino acids)
L-tryptophan	0.5 - 5.0
L-valine	3.0 - 14.5
L-arginine	3.0 - 12.0
L-histidine	2.0 - 7.0
Glycine	2.0 - 12.0
L-alanine	3.0 - 15.0
L-cysteine	0 - 1.0
L-aspartic acid	0 - 4.0
L-glutamic acid	0 - 7.0
L-glutamine	5.0 - 40.0
L-proline	1.5 - 5.5
L-serine	0.5 - 3.0
L-tyrosine	0.1 - 5.0

wherein a weight ratio of the total weight of branched chain amino acids (L-leucine, L-isoleucine and L-valine) to the total weight of L-glutamine is 0.11 to 7.50, a weight ratio of the total weight of branched chain amino acids to the total weight of amino acids is 0.18 to 0.46 and a weight ratio of the total weight of the non-essential amino acids to the total weight of the essential amino acids is 0.50 to 1.80.

Thus, the emphasis of the JP '762 claim is on the delivery of an essential amino acid, a non-essential amino acid and an oligopeptide. The disclosure of the JP '762 document goes on to describe the preparation of transfusion fluids having the oligopeptide and a complex mixture of amino acids.

The subject invention is preferable to that which is claimed in the JP '762 reference because the complex mixture of amino acids is not needed. Also, unlike the JP '762 technology, wherein the emphasis is on transfusion fluids, the simple but advantageous compositions of the subject invention can be readily formulated for enteric or parenteral administration.

The mere fact that the purported prior art could have been modified or applied in a manner to yield the applicant's invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127

(Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, “[b]oth the suggestion and the expectation of success must be founded in the prior art” *In re Dow Chemical Co.*, *supra* at 1531. In the references cited in support of the §103 rejection, one finds neither.

In view of the foregoing remarks and the amendment above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachment: Marked-up Version of Amended Claims

Marked-up Version of Substitute Claim AmendmentsClaim 1 (amended):

1. A peptide composition [comprising] consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation, wherein the arginine residue is the amino terminus of said dipeptide and the glutamine residue is the carboxy terminus of said dipeptide and wherein the dipeptide is present in said composition at a concentration of about 0.1% to about 25% by weight of said formulation.

Claim 13 (amended):

13. A method for promoting an increased mucosal IgA immune response [immunity to pathogens] in a human or animal, said method comprising administering to a human or animal [in need of such treatment] an effective amount of a dipeptide composition [comprising] consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation, wherein the arginine residue is the amino terminus of said dipeptide and the glutamine residue is the carboxy terminus of said dipeptide.